REMARKS

The Final Office Action mailed July 3, 2002 (hereinafter the Office Action), has been received and reviewed. Claims 1 through 52 are currently pending in the application, and claims 1 through 52 stand rejected. However, Applicants herein cancel claims 2 and 5 through 52 without prejudice or disclaimer, and Applicants have herein amended claims 1, 3 and 4. Applicants, therefore, respectfully request reconsideration of the application in light of the amendments and remarks set forth herein.

Claim Objections

Claims 18 and 36 are objected to in the Office Action due to the apparent misspelling of the term "interleukin," which is included in the claims. Applicants respectfully note, however, that claims 18 and 36 are cancelled herein without prejudice or disclaimer, and applicants respectfully request that the objection to these claims be withdrawn.

35 U.S.C. § 112 Rejections

Claims 39 through 52 are rejected in the Office Action under 35 U.S.C. § 112, first paragraph. Applicants respectfully note, however, that claims 39 through 52 are cancelled herein without prejudice or disclaimer, and Applicants respectfully request that the rejection of these claims under Section 112, first paragraph, be withdrawn.

Claims 1 through 52 are rejected in the Office Action under 35 U.S.C. § 112, second paragraph. With regard to these claims, it is asserted in the Office Action that the term "substantially" renders the terms "in-situ aggregation effect" and "improved bioavailability" indefinite. Applicants respectfully note, however, that claims 1, 3 and 4 as they are amended do not include the terms "substantially," "in-situ aggregation effect" or "improved bioavailability," and Applicants respectfully request that the rejection of claims 1, 3, and 4 under Section 112, second paragraph be withdrawn.

35 U.S.C. § 103(a) Obviousness Rejections

Each of pending claims 1 through 52 stands rejected under 35 U.S.C. § 103(a) ("Section 103") as being unpatentable over one or more of the following: Rudnic et al. (U.S. 5,952,004); Alex et al. (U.S. 6,352,717); Eckenoff et al. (U.S. 4,692,326); and Wong et al. (U.S. 5,324,280). However, because claims 2 and 5 through 52 are cancelled herein without prejudice or disclaimer, Applicants address such rejections only as they apply to claims 1, 3, and 4.

Applicants respectfully submit that the rejection of claims 1, 3, and 4 under Section 103 should be withdrawn. A rejection under Section 103(a) is improper and will be overturned unless a *prima facie* case of obviousness is established against the rejected claims. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). Applicants respectfully submit that none of the combinations of references cited in the Office Action provides evidence sufficient to properly establish the *prima facie* obviousness of any of claims 1, 3 or 4. Thus, Applicants respectfully request that the rejection of claims 1, 3 and 4 be withdrawn.

As is set forth in M.P.E.P. 706.02(j), a *prima facie* case of obviousness under Section 103 can not be established unless three criteria are met:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The examiner bears the burden of establishing these three criteria based on the prior art.

In the present case, Applicants respectfully submit that the combined teachings of the references cited against claims 1, 3 and 4 do not teach or suggest each of the claim limitations recited in the claims as they are amended. In particular, Applicants respectfully note that the combined teachings of the references cited in the Office Action do not teach or suggest a

controlled release dosage that (1) includes a self-emulsifying antiviral formulation as recited in the rejected claims and (2) is configured to deliver the antiviral formulation as required by any one of the rejected claims. More specifically, Applicants respectfully submit that the combined teachings of the references cited against claims 1, 3 and 4 do not teach or suggest a controlled release dosage form that includes a liquid, self-emulsifying antiviral drug formulation composed of up to 60 wt% of a solubilized antiviral drug. In addition, Applicants respectfully submit that the combined teachings of the references cited in the Office Action fail teach or suggest a dosage form that is configured to administer an antiviral formulation as defined in claims 1, 3 and 4 such that a therapeutically effective dose of antiviral drug is delivered over at least 4, 12, or 24 hours at the rates specified in the rejected claims. Therefore, Applicants respectfully submit that the combined teachings of the references cited in the Office Action do not meet all the criteria necessary to establish the *prima facie* obviousness of claims 1, 3 and 4, and Applicants respectfully request that the rejection of these claims be withdrawn.

CONCLUSION

Claims 1, 3 and 4 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully Submitted,

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Attachments: Version of Claims with Markings to Show Changes Made
SEW/eg
Date: October 3, 2002

Version of Claims with Markings to Show Changes Made

1. (Amended) A sustained release oral dosage form comprising a liquid, self-emulsifying antiviral drug [composition which composition is substantially free of *in-situ* aggregation effect of the antiviral drug and provides substantially improved bioavailability of said antiviral drug] formulation comprising up to 60 wt% of a solubilized antiviral drug, wherein the dosage form is configured to administer a therapeutically effective dose of said antiviral drug over a period of at least 4 hours after oral administration with no more than 30% by weight of said drug formulation being released within the first 1 hour after oral administration.

3. (Amended) [The dosage form of claim 1 which administers] A sustained release oral dosage form comprising a liquid, self-emulsifying antiviral drug formulation comprising up to 60 wt% of a solubilized antiviral drug, wherein the dosage form is configured to administer a therapeutically effective dose of said antiviral drug over a period of at least 12 hours after oral administration with no more than 30% by weight of said drug [composition] formulation being released within the first 4 hours after oral administration.

4. (Amended) [The dosage form of claim 1 which administers] A sustained release oral dosage form comprising a liquid, self-emulsifying antiviral drug formulation comprising up to 60 wt% of a solubilized antiviral drug, wherein the dosage form is configured to administer a therapeutically effective dose of said antiviral drug over a period of 24 hours after oral administration with no more than 30% by weight of said drug [composition] formulation being released within the first 12 hours after oral administration.